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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,393	01/10/2001	Takuya Seko	Q62550	2333

7590

03/24/2003

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EXAMINER

HUANG, EVELYN MEI

ART UNIT

PAPER NUMBER

1625

DATE MAILED: 03/24/2003

11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/743,393

Applicant(s)

SEKO ET AL.

Examiner

Evelyn Huang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,9-12 and 16-18 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-5,9,12 and 16-18 is/are rejected.
- 7) ☒ Claim(s) 10 and 11 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

1. Claims 1-5, 9-12, 16-18 are pending. Claims 6-8, 13-15 have been canceled according to the amendment filed on 12-19-2002.

Claim Rejections - 35 USC § 112(2)

2. The rejection for Claims 1-5, 8-9, 12-15 under 35 U.S.C. 112, second paragraph, is withdrawn because the amendment has obviated the rejection.

Claim Rejections - 35 USC § 112(1)

3. The rejection for Claims 1-5, 9, 12 under 35 U.S.C. 112, first paragraph, is maintained for reasons of record. The rejection is applicable to new claims 16-18.

The specification is only enabling for the compounds of claims 10-11 and its use for treatment of the diseases recited in claim 18. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate with the scope of claims.

Applicant argues that applicant is not limited to tested examples provided in the specification. A specification may be enabling without any working examples.

While applicant's claims are not required to be limited to the examples and working examples are not required for enablement of the disclosure, the scope of the claims should be commensurate with that of the objective enablement. In the instant case, the preparation of examples are limited to compounds wherein R1 being thiazolidinyl, oxazolidinyl or pyrrolidinyl, R3 being cyclopentylmethyl or cyclohexylmethyl and R4 being piperidinyl, whereas the claims are directed to R1 and R4 being any heterocyclic, and R3 is any carbocyclic, which may be further substituted with carbocyclic and/or heterocyclic and where adjacent substituents together form a further heterocyclic. Starting material and the process of making the diverse compounds embraced by the claims but not fully described are not seen but required. Sources are

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particularly pertinent because absent sources, the public is offered mere language, rather than enablement. *Ex parte Moersch* 104 USPQ 122. *In re Howarthe* 210 USPQ 689.

Applicant contends that there is no requirement that the instant compounds with all possible claimed substituents will retain the same properties. Even if the claims encompass inoperative species, the claims would comply with the enablement requirement as long as there is no undue experimentation.

While some experimentation is permitted and every claimed embodiment need not be shown to possess the asserted activity, there should be a showing commensurate in scope with the claims. As stated in *In re Cavallito* 127, USPQ 202, “where the applicant seeks to obtain a monopoly in exchange for his disclosure of a group of compounds, there should be a disclosure which gives reasonable assurance that all, or substantially all of them are useful....an applicant is not entitled to a claim for a large group of compounds merely on the basis of a showing that a selected few are useful and a general suggestion of a similar utility in the others”. Furthermore, in the instant calcium channel blocker art, where there is a high degree of unpredictability exists, the required disclosure will be greater than for the disclosure of an invention involving a predictable factor such as a mechanical or electrical element. *In re Vaeck*, 20 USPQ 2d 1438. The instant claims encompass compounds of vastly diverse structures, some quite removed from the examples limited to compounds wherein R1 being thiazolidinyl, oxazolidinyl or pyrrolidinyl, R3 being cyclopentylmethyl or cyclohexylmethyl and R4 being piperidinyl. Because of the high degree of unpredictability in the art, one of ordinary skill in the art would have no basis to extrapolate the results to compounds structurally dissimilar to the examples, and expect that the variety of these structurally diverse compounds embraced by the claims would share the same biological activities.

Although the procedures for the determination of inhibitory activity on N-type calcium channel are found on pages 82-83 of the specification, and Table 4I (page 83) shows the inhibitory effects for the compounds of Example 11 and 11(2), these procedures do not indicate the criteria for predicting the occurrence of these disorders, nor do they provide the guidance on how to *prevent* the onset of these calcium channel-mediated disorders in a subject.

In conclusion, in view of the state of the art, the high degree of unpredictability of the art, the limited working examples, the scope of the claims does not commensurate with that of the

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objective enablement, undue experimentation would be required for one of ordinary skill in the art to make and use the invention as claimed.

Double Patenting

4. The provisional obviousness-type double patenting rejection over the corresponding claims of copending Application No. 09/462447 or 09/720433 is withdrawn upon reconsideration in view of the amendment and applicant's remarks. The instant claims do not contain overlapped subject matter with the copending claims.

Allowable Subject Matter

5. Claims 10-11 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Amber (EP 805147, PTO-1449) discloses a N-substituted alpha amino acid amide as calcium channel modulator. While the instant thiazolidinyl as R1 is generically disclosed by Amber, an example of thiazolidinyl is not described. Furthermore, Amber's R25R26 are each hydrogen or alkyl whereas the corresponding R4 of the instant is a heterocyclic or alkyl substituted with heterocyclic.

Esser (5596000, PTO-1449) generically discloses the instant compound. However, an example with thiazolidinyl is not described. Lacking is the motivation to select the thiazolidinyl to arrive at the instant invention.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

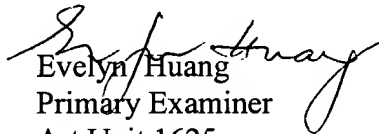
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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 703-305-7247. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on 703-308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


Evelyn Huang
Primary Examiner
Art Unit 1625

March 21, 2003